Remarks

Claim 23 has been amended to recite "[t]he composition according to claim 14 wherein the pharmaceutical composition is a solid unit oral dosage form, the catechin is (-) epigallocatechin gallate and (-) epigallocatechin gallate is present in an amount of from about 10 mg to about 2000 mg, and wherein the PPARγ ligand is present in an amount of from about 1 to about 1000 mg." Support is found in the Specification at, for example, paragraph 17, lines 1-7; and original claim 17. See In re Gardner, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

New claim 24 recites, "The composition according to claim 14 wherein the pharmaceutical composition is a solid unit oral dosage form for effecting glucose tolerance and preventing body weight gain or adipose tissue weight gain associated with use of a PPARγ ligand and the catechin and the PPARγ ligand are present in glucose lowering amounts." Support is found in the Specification at, for example, paragraph 11, paragraph 12, lines 1-9, paragraph 10, and Example 1 (paragraphs 19-35).

New claim 25 is added which recites, "A pharmaceutical composition for effecting glucose tolerance comprising an effective amount for reducing fasted state glucose concentration of a catechin found in green tea, and an effective amount of a peroxisome proliferator-activated receptor gamma (PPARγ) ligand selected from the group consisting of thiazolidinediones, ligustilide and phytanic acid, wherein the amounts of the catechin and the PPARγ ligand are such that fasted state glucose is lowered to an extent greater than that for either the catechin or the PPARγ ligand."

Support is found in the Specification at, for example, paragraphs 30 and 31, paragraph 34, lines 7-10 and 16-17, paragraph 35, and paragraph 17, lines 9-11.

New claim 26 is added which recites, "A pharmaceutical composition for effecting glucose tolerance comprising an effective amount of a catechin found in green tea, and of a peroxisome proliferator-activated receptor gamma (PPARγ) ligand selected from the group consisting of thiazolidinediones, ligustilide and phytanic acid, wherein the effective amount of each of the catechin and the PPARγ ligand in combination reduces fasted state glucose concentration and prevents body weight gain or adipose tissue weight gain associated with use of a PPARγ ligand." Support is found in the Specification at, for example, paragraph 10 and Example 1 (paragraphs 19-35).

New claims 27-30 depend from amended claim 23 and new claims 24, 25 and 26, respectively. Support is found in the Specification at, for example, paragraph 5, lines 1-4; paragraph 15, lines 1-3; and Example 1B at paragraphs 22-24 and Table 2.

New claims 31 and 32 depend from new claims 25 and 26. Support is found in the Specification at, for example, paragraph 17, lines 1-7; and original claim 17. (Id.)

New claims 33 and 34 both depend from amended claim 23. Support for new claim 33 is found in the Specification at, for example, Examples 2-4 at paragraphs 36-48, and at paragraph 17, lines 1-9. Support for new claim 34 is found in the Specification at, for example, paragraph 17, lines 1-7; and original claim 17. (Id.)

No new matter is added.

It is also submitted that the amendments including new claims do not present new issues. Entry of the amendments is respectfully requested.

Anticipation Rejection

Claims 14, 15, 17, 21, and 22 were rejected under 35 U.S.C. § 102(b) as being anticipated by Cui (CN 1120953, Derwent Abstract provided) ("Cui"), with evidence provided by Ahmad et al. (Nutrition Reviews, March 1999) ("Ahmed") and Ko (Jap. J. Pharmacol., 1980) ("Ko"). (Paper No. 0508 at 2.)

Cui is summarized in the Response to Office Action Including Amendment dated January 25, 2008 ("the prior Response") on pages 12-13.

In making the rejection, the Examiner asserted that the reasons for the rejection are "the reasons set forth in the previous Office action." (Id.)

In addition, the Examiner asserted as follows concerning both the § 102 rejection and § 103 rejection (addressed below):

> Applicants' arguments concerning the USC 102(b) and USC 103 rejections above have been carefully considered but are not deemed to be persuasive of error in the rejections. Applicants argue that the Cui reference comprises other additional ingredients. However, the instantly claimed composition is one which comprises the instantly claimed ingredients. Accordingly, this open language (i.e., "comprising") permits the inclusion other ingredients therein. Applicants also argue that the Cui reference lacks an "identity of invention" with the claimed composition which comprises a catechin found in green tea and a PPARγ ligand – such as the elected species: ligustilide. However, for the reasons fully set forth in the previous Office action, the health-benefiting drink composition taught by Cui inherently comprises a catechin such as epigallocatechin gallate (inherently contained within green tea) and ligustilide (inherently contained within *Ligusticum wallichii)* - including being present within such a composition so as to provide the broad dosage ranges of each therein - as best understood by the claim language, as drafted (e.g." the instant claim language does not define in a positive manner as to what such a dosage of EGCG and/or ligustilide is in relation to). Applicants further argue the claim

> composition, as instantly amended, is now defined as being a pharmaceutical composition and that the Cui reference fails to disclose a pharmaceutical composition. However, the health-benefiting drink (having the various therapeutic functional effects disclosed therein) taught by Cui clearly reads upon a pharmaceutical composition. (Id. at 3.)

In addition, the Examiner asserted that "Ahmad et al. and Ko references are not being cited as prior art within the USC 102(b) and 103 rejection above but instead are being cited as evidence to show inherent properties of green tea and *Ligusticum wallichii* within the Cui composition." (Id. at 4.)

The arguments presented in the prior Response are incorporated here.

It is respectfully submitted that the Examiner has erred in having asserted that "the health-benefiting drink (having the various therapeutic functional effects disclosed therein) taught by Cui clearly reads upon a pharmaceutical composition." (Id.) Cui discloses, *inter alia*, that "[t]he drink has obvious hypolipaemic, blood pressure depressing and hypoglycemic *functions*...". (emphasis added.) In terms of glucose tolerance effects, Cui provides nothing more than a blanket statement of possible health benefiting "functions". Regarding Cui's disclosure that "[t]he drink ... can improve microcirculation and can prevent and cure coronary heart disease, heart disease and other cardiovascular diseases as well as cancer", such blanket statements of health-benefiting effects also do not rise to a disclosure of a pharmaceutical composition. Cui provides no scientific evidence or reasoning pertaining to use of the disclosed drink for treatment of a disease. Moreover, as has been noted, additional herbal or botanical ingredients are disclosed by Cui as included in the beverage. One skilled in the art would understand Cui as disclosing a mixture of ingredients with a promotional

statement of the compositions' possible health benefits, and not a pharmaceutical composition suitable for treatment or prevention of a disease. To assert that Cui encompasses a pharmaceutical composition strains credulity.

When a document discloses a pharmaceutical composition, it indicates to one skilled in the art that that such a product would be administered to patients with a recognized need for treatment of the recited conditions, and that the contents of that product would be effective in bringing about the intended treatment use. *Jansen v. Rexall Sundown, Inc.,* 342 F.3d 1329, 1334-35 (Fed. Cir. 2003) ("Use of an over-the-counter product ... is quite different from the use of a product pursuant to a prescription from a medical doctor. In the latter case, a prescription is evidence of a diagnosis and a knowing need to use the product for the stated purpose.") As noted regarding Cui, however, the disclosure would be understood by one skilled in the art as nothing more than a promotional statement of possible health benefits of a beverage, and not a disclosure of a composition that is a pharmaceutical composition.

It is noted that the Examiner referred to Cui's "composition containing green tea (10-25%) and *Ligusticum wallichii* '... of 5 total ingredients as a ***health-benefiting drink***." (The prior Office Action, Paper No. 20070713 at 6) (emphasis added.) Interestingly, the Examiner did ***not*** refer to Cui's beverage composition as a disease-curing or disease-preventing composition.

In view of the Examiner's erroneous characterization of Cui as allegedly disclosing a pharmaceutical composition, the rejection is deficient and must be withdrawn.

Moreover, Cui is not an enabling document for any of the current or newly amended or submitted claims. Relative amounts of a catechin found in green tea and a PPARγ ligand that would be effective in treating or preventing ***any disease***, such as for example, hypoglycemia, are notably lacking in Cui. Cui thus clearly lacks an enabling disclosure for a pharmaceutical composition. Furthermore, Cui lacks any disclosure of effective amounts for reducing fasted state glucose concentration of a catechin found in green tea, and an effective amount of a peroxisome proliferator-activated receptor gamma (PPARγ) ligand, wherein the amounts of the catechin and the PPARγ ligand are such that fasted state glucose is lowered to a extent greater than that for either the catechin or the PPARγ ligand. In addition, Cui lacks any disclosure of a composition for effecting glucose tolerance comprising an effective amount for reducing fasted state glucose concentration of a catechin found in green tea, and of a peroxisome proliferator-activated receptor gamma (PPARγ) ligand, wherein the effective amount of each of the catechin and the PPARγ ligand in combination reduces fasted state glucose concentration and prevents body weight gain or adipose tissue weight gain associated with use of a PPARγ ligand. Thus, Cui fails to teach how to make the presently claimed compositions.

For a § 102 rejection, a reference must be enabling to place the allegedly disclosed subject matter in the possession of the public. See *Akzo N.V. v. United States Int'l Trade Comm'n*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987). Clearly, Cui is not enabling for the claimed subject matter. Cui cannot properly be applied as a reference under § 102 and for this additional reason, the rejection cannot stand.

We further note that the rejection is legally deficient. A proper rejection under §102(b) requires that the Examiner demonstrate that each and every element of a claimed invention be present ***in a single prior art reference*** as arranged in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir 1984). Here, the Examiner attempts to rely on Ahmad and Ko to fill in the factual gap in Cui that there is no disclosure of enabling amounts in order to make the claimed pharmaceutical compositions.

The MPEP recognizes three situations where multiple documents may be relied upon in a §102 rejection: (1) to prove the primary reference is enabled, (2) to explain the meaning of a term used in the primary reference, and (3) to show that a characteristic not disclosed in the primary reference is inherent. *See*, e.g., MPEP §2131.01. None of these circumstances are present here.

Although the Examiner asserted that Ahmed and Ko are cited as evidence "to show inherent properties of green tea and *Ligusticum wallichii* within the Cui composition", evidencing the asserted properties still does not provide an enabling disclosure in Cui for the present claims.

For each of the foregoing reasons including the arguments presented in the prior Response, it is submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

Obviousness Rejections

A. Cui with evidence provided by Ahmad and Ko

Claims 14, 15, 17, 21, and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cui, with evidence provided by Ahmad and Ko. (Paper No. 0508 at 2.)

In making the rejection, the Examiner asserted that the rejection was made "for the reasons set forth in the previous Office action." (Id.)

The Examiner had made the assertions quoted above in the section addressing the § 102 rejection regarding both the §§ 102 and 103 rejections. The Examiner made the additional assertions:

> Applicants additionally argue that the claimed combination provides unexpectedly improved and superior results (e.g., as shown in Example I of the instant specification with respect to a therapeutic pharmaceutical composition comprising ligustilide and EGCG). Based on this argument, it would appear that Applicants' invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon highly dependent upon specific proportions and/or amounts of each particular ingredient (e.g., claimed in a positive manner so that the dosages of each ingredient which actually provide such unexpected results are clearly and adequately defined within the independent claim). However, please note that any mixture of ingredients embraced by the claims which does not exhibit an unexpected result (including the composition defined by the instant claim language, as drafted) is deemed obvious and, thus, unpatentable for the reasons set forth above. (Id. at 3-4.)

Arguments submitted in the prior Response are incorporated here.

Beyond looking at the cited documents to determine if any of them suggests doing what the inventors have done, one must also consider if the art provides the required expectation of succeeding in that endeavor. See *In re Dow Chem. Co. v. American Cyanamid Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). "Obviousness does not require absolute predictability, but a reasonable expectation of success is necessary." *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976). Furthermore, the U.S. Patent and Trademark Office Examination Guidelines at page 57527 provide the following guidance to Examiners: "In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge". However, no such motivation or expectation of success can be found in the cited documents.

It is submitted that the present claims are coextensive with the unexpectedly improved and superior results disclosed in the Specification. As stated in the Specification:

> ...***it has surprisingly been found*** that the combination of EGCG and PPARγ ligands results in amelioration and/or elimination of the undesirable side effect of PPARγ agonist-induced adipocyte differentiation, which leads to body fat gain. Thus, PPARγ ligands ... can be used, in combination with EGCG to treat Type 2 diabetes mellitus and to inhibit/reduce the PPARγ agonist-induced adipogenesis, while maintaining or increasing the glucose lowering effects.
>
> (Page 2, paragraph 10) (emphasis added).

As noted in the prior Response, all of the experimentals of Example 1 demonstrate these findings. Regarding elimination of the undesirable side effect of

PPARγ ligands, for instance, it is disclosed in paragraph 29 with reference to the data disclosed in Table 3 that "[a]dministration of rosiglitazone ***significantly*** increased body weight and adipose tissue weight." Paragraph 29, lines 2-4 (emphasis added). It is then disclosed that "[a]dministration of EGCG [only] ***moderately decreased body weight and adipose tissue weight*** compared to control mice." Paragraph 29, lines 4-6 (emphasis added). Yet the Specification discloses that "[c]ombined administration of EGCG and rosiglitazone ***totally abolished the increase in body weight and adipose tissue weight induced by rosiglitazone alone.***" Paragraph 29, lines 6-8 (emphasis added). Given the moderate effect of EGCG alone in decreasing body weight and adipose tissue weight, one skilled in the art would not expect that the otherwise significant increase in body weight and adipose tissue weight seen with a PPARγ inhibitor alone, to be ***"totally abolished"*** when EGCG is used with the PPARγ inhibitor. Moreover, as is further disclosed, "the combined administration resulted in a moderate reduction of body weight and adipose tissue weight compared to control mice. The effect was similar to the effect of the administration of EGCG alone." (Paragraph 29, lines 9-12.) One skilled in the art would not expect that the addition of EGCG with a PPARγ inhibitor as claimed would even moderately ***reduce*** body weight and adipose tissue weight compared to control mice, as though in respect of this adverse effect of PPARγ inhibitors, EGCG alone was administered.

Regarding the effect on glucose tolerance, paragraphs 30 and 31 and Table 4 of the Specification disclose a study testing fasted glucose levels in db/db mice treated with EGCG, rosiglitazone and a combination of the two. Both EGCG and rosiglitazone individually reduced fasted glucose levels. Rosiglitazone reduced levels to

a greater extent than did EGCG (about 66% reduction compared to control vs. about 54% reduction compared to control, respectively). The combined treatment with EGCG and rosiglitazone, however, "led to a ***significantly improved glucose tolerance*** as compared to mice treated with either rosiglitazone or EGCG alone", and it is calculated as a 73% decrease as compared to control (Paragraph 31, lines 8-11) (emphasis added.) Furthermore, Table 4 indicates that the area under the curve (AUC) in the oral glucose tolerance test determined for the combination therapy was ***"significantly different from [the AUC determined for] rosiglitazone"***. (emphasis added.)

It is also noted that a solid unit oral dosage form has a practical limit on the amount of substances for inclusion in order to produce a dosage form that may be swallowed by a patient. Cui discloses the presence of five required ingredients. It would not be feasible to provide a solid unit oral dosage form of Cui's ingredients in the amounts disclosed. Cui does not disclose or suggest any of the claims directed to a solid unit oral dosage form pharmaceutical composition.

In view of the foregoing, it is submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

B. Morre and Zhao

Claims 14, 15, 17 and 21-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Morre et al., U.S. Patent No. 6,410,061 ("Morre") and Zhao, U.S. Publication 2003/0165580 ("Zhao").

Morre disclose "methods and compositions of treating cancer or solid tumors comprising the administration of a therapeutically effective amount of catechins... to a mammal in need of such therapy." (Abstract, lines 1-4.)

Zhao discloses a "pharmaceutical composition for treating and preventing gynecological disease and increasing immune function." (Abstract, lines 1-3.)

In making the rejection, the Examiner asserted that "Morre et al. beneficially teach a pharmaceutical composition (including, e.g., in a solid unit dosage form such as a tablet or capsule) useful for treating various cancers including ovarian cancer, which comprises one or more green tea catechins such as epigallocatechin gallate as the active ingredient(s) therein. Morre et al. also teach that an effective daily dosage of epigallocatechin gallate is about 0.15 mg to about 1500 mg per kg body weight (within the instantly claimed dosage amount - as best understood). See entire document including Abstract; col 6, line 29 - col 17, line 35; and claims. Morre et al. do not teach the inclusion of ligustilide therein." (Id.)

In making the rejection, the Examiner asserted that "Zhao beneficially teaches a pharmaceutical composition (including, e.g., in a solid unit dosage form such as a tablet or capsule) useful for treating/controlling gynecological diseases including cancers such as ovarian cancer, which comprises ligustilide as the active ingredient therein. Zhao also teaches that an effective daily dosage of ligustilide is 1-10 mg per kg body weight which - as disclosed by Zhao, corresponds to 50-500 mg/adult/dose for a 50 kg adult (within the instantly claimed dosage amount - as best understood). See entire document including Abstract, paragraphs [0017]-[0019], [0036]-[0037], [0090]-[0093], Examples, and claims." (Id. at 5.)

The Examiner concluded as follows:

> It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant

> ingredients for their known benefit since each is well known in the art for the same purpose (i.e., for treating cancer including ovarian cancer) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The idea for combining them flows logically from their having been used individually in the prior art. [citations omitted.] Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular (e.g., active) ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable." (Id.)
>
> Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him/her as a guide
>
> From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention: Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary. (Id. at 5-6.)

It is well settled the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and modify the document(s) relied on by the Examiner as evidence of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731-32 (2007) (the obviousness "***analysis should be made explicit***" and the teaching-suggestion-motivation test is "***a helpful insight***" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to modify document(s) must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion test "***must be based on objective evidence <u>of record</u>***." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). *See also Examination Guidelines for Determining Obviousness*, 72 Fed. Reg. 57526, 57528 (October 10, 2007) ("The key to supporting any rejection under 35 USC § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.").

Respectfully, we submit that the rejection is devoid of a proper § 103 analysis in support of the proposed modification. All that is there are conclusory statements such as the assertion that "[i]t would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose (i.e., for treating cancer including ovarian cancer) ...". (Paper No. 0508 at 5.)

Here, what the rejection should have done, but did not, was to explain on the record ***why*** one skilled in this art would modify the disclosure of Morre and/or Zhao

in the manner proposed by the Examiner to arrive at the claimed process. As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (citing *KSR*) (indicating that "it remains necessary to identify ***some reason*** that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound") (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). But this is precisely what the Examiner has done here. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). In doing so we observe that obviousness cannot be based upon speculation, nor can obviousness be based upon possibilities or probabilities. Obviousness ***must*** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). Further, "to establish *prima facie* obviousness of a claimed invention, ***all claim limitations must be taught or suggested by the prior art***." MPEP § 2143.03 (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)) (emphasis added).

It is submitted that neither Morre nor Zhao provides a suggestion or motivation to combine these documents in order to achieve a pharmaceutical

composition for effecting glucose tolerance. And, nowhere does Morre or Zhao disclose or suggest dosages of each of the catechin and PPARγ ligand for a pharmaceutical composition for effecting glucose tolerance.

Furthermore, even if the combination were proper, which we assert it is not, one skilled in the art would not have expected to be able to achieve a pharmaceutical composition for effecting glucose tolerance as claimed wherein the effective amount of each of the catechin and the PPARγ ligand in combination reduces fasted state glucose concentration and prevents body weight gain or adipose tissue weight gain associated with use of a PPARγ ligand. Nor would one skilled in the art have expected to achieve a pharmaceutical composition for effecting glucose tolerance as claimed wherein the amounts of the catechin and the PPARγ ligand are such that fasted state glucose is lowered to a extent greater than that for either the catechin or the PPARγ ligand. Arguments presented in section A above are incorporated here.

It is submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

Double Patenting Rejections

A. Application No. 10/533,858

Claims 14, 15, 17 and 21-23 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-45 of copending Application No. 10/533,858. (Paper No. 0508 at 6.)

In making the rejection, the Examiner asserted that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other

because the claims of the copending Application are drawn to compositions comprising epigallocatechin gallate and the non-elected species phytanic acid therein." (Id.)

It is noted that Application No. 10/533,858 has been abandoned. Accordingly, it is submitted that the present rejection has been rendered moot. Withdrawal of the rejection is requested.

B. Application No. 10/556, 199 in view of Hara

Claims 14, 15, 17 and 21-23 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-24 of copending Application No. 10/556,199 ("the '199 Application") in view of Hara et al., U.S. Patent No. 5,318,986 ("Hara").

Hara disclose "[a] method of providing a therapeutic effect for diabetes in a human ... mediated by inhibiting the activity of α-amylase in the digestive tract ... comprising orally administering to said human in the form of a powder, tablet or capsule 0.3g to 10 g per day of at least one gallated catechin compound or theaflavin compound...". (Claim 1, lines 1-7.)

In making the rejection, the Examiner asserted that "the cited claims of Appl. No. '199 is [sic] drawn to a pharmaceutical composition (for the intended purpose of treating/preventing diabetes) comprising ligustilide therein. Hara et al. teaches the use of a composition comprising epigallocatechin gallate (from green tea) for effectively treating diabetes (see entire document). Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the claimed antidiabetic ligustilide pharmaceutical composition set forth in Appl. No. '199 with epigallocatechin gallate based upon the beneficial teachings provided by Hara et

al. with respect to epigallocatechin gallate also being an effective anti-diabetic agent." (Paper No. 0508 at 7.)

The remarks provided in the prior Response are incorporated here.

In addition, even if a combination of the '199 Application and Hara were proper, which we submit it is not, one skilled in the art would not have expected to achieve a pharmaceutical composition for effecting glucose tolerance as claimed wherein the effective amount of each of the catechin and the PPARγ ligand in combination reduces fasted state glucose concentration and prevents body weight gain or adipose tissue weight gain associated with use of a PPARγ ligand. Nor would one skilled in the art have expected to achieve a pharmaceutical composition for effecting glucose tolerance as claimed wherein the amounts of the catechin and the PPARγ ligand are such that fasted state glucose is lowered to a extent greater than that for either the catechin or the PPARγ ligand. Arguments presented in section A of the responses to the § 103 rejections above are incorporated here.

It is submitted that the obviousness-type double patenting rejections have been rendered moot. Reconsideration and withdrawal are requested.

It is respectfully submitted that the comments and amendments set forth above place the application in condition for allowance or better form for appeal. Accordingly, entry of the amendments is proper. And, withdrawal of the rejections and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box. 1450 Alexandria, VA 22313-1450, on November 12, 2008.

Eileen M. Ebel, Reg. No. 37,316

Respectfully submitted,

By: _____

Eileen M. Ebel
Registration No. 37,316
BRYAN CAVE LLP
1290 Avenue of the Americas
New York, NY 10104
(P) (212) 541-2194
(F) (212) 541-4630